

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION**

CHARLES GRAHAM, <i>et al.</i>,)	
)	
Plaintiffs,)	
)	No. 3:16-cv-01954
v.)	
)	
TONY C. PARKER, <i>et al.</i>,)	
)	
Defendants.)	

PRETRIAL ORDER

I. AMENDMENT OF THE PLEADINGS

The parties state, and the Court orders, that the pleadings filed in this matter are supplanted by, and amended to conform with, this Pretrial Order. The parties stipulate that Dr. Marina Cadreche (former) Assistant Commissioner of Rehabilitative Services for the Tennessee Department of Correction will be dismissed as a defendant pursuant to Fed. R. Civ. P. 41(a).

II. JURISDICTION

The Court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331, 1343(a) as the Complaint raises a federal question. There are no jurisdictional questions to be resolved.

III. SUMMARY

A. PLAINTIFFS' SUMMARY

Hepatitis C is a serious, highly infectious disease that is ultimately fatal. Beginning in 2011 the Federal Drug Administration approved medications known as Direct Acting Antivirals (“DAA”) that have a 96% “cure rate” of an HCV infection. Since then, DAA treatment has become the standard of care for patients with chronic HCV. As of April 2019, 4,872 inmates had diagnoses of HCV infection. The number of inmates with an undiagnosed HCV infection is unknown.

The Eighth Amendment to the United States requires the state to ensure that inmates receive adequate medical care. *See Farmer v. Brennan*, 511 U.S. 825, 832 (1994). An Eighth Amendment violation is shown by “deliberate indifference to serious medical needs of prisoners.” *Estelle v. Gamble*, 429 U.S. 97, 104 (1976). Defendants’ Chronic HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C (“HCV Guidance”) establishes the thresholds for which inmates are eligible for DAA treatment. The TDOC Advisory Committee on HIV and Viral Hepatitis Prevention and Treatment (“TACHH”), holds the exclusive authority to determine which inmates will actually receive treatment.

TACHH history shows Defendants’ actual practical approach to treatment HCV positive inmates. TACHH only reviews an average of 20 individual files per month and spends on average only 3 minutes reviewing an inmate’s medical records before deciding whether or not that person will receive treatment. In effect, TACHH’s practice is to ration DAAs to infected inmates based on their costs, rather than the needs of the patient. The result is that, on average, only 96 of the 4,000 plus known cases of HCV are approved for treatment in a year. Even if TACHH began approving an average of 50 inmates per month for DAA treatment, it would take eleven years to

treat all known cases of HCV. Under this scheme, inmates have and will continue to die before receiving treatment.

For those reasons, and those to be demonstrated at trial, Plaintiff will prove that Defendants' policy and practices for treating HCV violate the Eighth Amendment and will ask the court to grant them injunctive relief to cure this constitutional violation.

B. DEFENDANTS' SUMMARY

To obtain declaratory and injunctive relief, the Plaintiff Class must prove that the Defendant officials' current practices and procedures related to all cHCV-infected inmates are unconstitutional. The Class must prove how each official is connected to, or has responsibility for, alleged constitutional violations. The claims against Defendant Parker must fail as he is not connected to, or responsible for, for adopting or implementing such TDOC medical-related practices and procedures.

The Current Guidance at issue implements systems, practices and procedures designed to identify HCV-infected inmates, to monitor them periodically for signs of disease progression, and to prioritize treatment with DAAs where certain thresholds of disease progression or other complicating factors are indicated. Unless the latter factors are present, Class members cannot demonstrate that they have a sufficiently serious medical need to require pharmaceutical intervention under the objective component of deliberate indifference analysis. Practice under the Current Guidance is not so woefully inadequate as to amount to "no treatment at all." The Class cannot prove that, in applying the Current Guidance, Dr. Williams subjectively acts with deliberate indifference to their serious medical needs nor is the Class consciously exposes the Class to an excessive risk of serious harm. Where pharmaceutical intervention is not medically necessary, and

therefore not constitutionally required, the Court may properly consider the limited availability of medical resources.

The Class contends that universal DAA treatment is constitutionally required. The medical judgment of Dr. Williams, and the opinion of Defendants' experts' is that evidence-based medicine has never validated the efficacy of DAAs in preventing end stage liver disease—the desired outcome. The Current Guidance provides constitutionally adequate treatment as needed. The AASLD-IDSA guidelines which advocate universal treatment are untrustworthy, aspirational, and should not be followed as treatment requirements. Where, as here, there is robust and substantial good faith disagreement dividing respected members of the expert medical community there can be no Eighth Amendment violation.

V. ISSUES

A. PLAINTIFFS' STATEMENT OF THE ISSUES:

1. What is the standard of medical care for the treatment of HCV;
2. What are the Tennessee Department of Correction and Defendant's policies and procedures governing the provision of medical treatment for prisoners infected with HCV;
3. Whether infection with HCV constitutes a serious medical need for medical care which is obvious even to a lay person;
4. Whether such medical care is a right guaranteed by the U.S. Constitution;
5. Whether Defendants acted under color of state law in depriving the Class of such medical care;
6. Whether any or all of the Defendants perceived facts from which they may infer a substantial risk to the class members;
7. Whether any or all of the Defendants did in fact draw those inferences;

8. Whether any or all of the Defendants disregarded the risk perceived;
9. Whether any or all of the Defendants have acted with deliberate indifference to the class members' serious medical needs;
10. Whether Class members face the real and immediate threat of repeated injury from Defendants' unconstitutional policies and practices so as to necessitate the Court to fashion injunctive and declaratory relief.

B. DEFENDANTS' STATEMENT OF THE ISSUES:

1. Whether Plaintiffs can establish by a preponderance of the evidence that individuals with no fibrosis (F0), mild fibrosis (F1), or certain comorbid conditions associated with increased risk of liver damage have a sufficiently serious medical need to require pharmaceutical intervention under the objective component of deliberate indifference analysis.
2. Whether Plaintiffs can establish by a preponderance of the evidence that either Defendant Parker or Defendant Williams are subjectively indifferent to the serious medical needs of inmates in the custody of the Tennessee Department of Correction by engaging in active monitoring of chronic HCV infection in individuals without cirrhosis (F4 on the Metavir scale), advanced fibrosis (F3), or certain comorbid conditions in conformity to the 2019 HCV Guidance.
3. Whether Plaintiffs can establish by a preponderance of the evidence that either Defendant Parker or Defendant Williams are subjectively indifferent to the serious medical needs of inmates in the custody of the Tennessee Department of Correction by following the 2019 HCV Guidance with regard to the evaluation and management of the serious medical needs of chronic HCV-infected inmates in the custody of the Tennessee Department of Correction.

VI. RELIEF SOUGHT

Plaintiffs request that the Court rule that the Defendants' practices and policy for the treatment of Class Members for HCV infection violates the Eighth Amendment and for the Court to enter an injunction compelling Defendant to treat all inmates with chronic HCV in accordance with the prevailing medical standards of care regardless of their stage of cirrhosis or the cost of treatment. Plaintiffs requests that the Court's injunction compel the treatment of all class members in an expeditious and orderly manner beginning with Class Members with life threatening or the most severe complications from HCV and moving to those with less severe complications until all Class members have received treatment. Defendant should treat inmates designated F4 immediately, treat all inmate designated F3 within six months, and all other inmates within one year. Plaintiff further asks that the injunctive relief include continuing treatment for inmate's diagnosis with chronic HCV who meet the class definition. Such treatment should occur as soon as possible after testing confirms chronic HCV infection and in no case should treatment begin after two month of confirming such a diagnosis. Finally, to ensure compliance with the Court's order, Plaintiffs asks that the Court order routine reporting of the progress of treatment of class members and appoint a monitor, at Defendants' expense, to oversee the treatment of Class members. Finally, Plaintiffs asks they be awarded discretionary costs and attorneys' fees as provided by law.

Defendants seek dismissal with prejudice.

VII. EVIDENTIARY DISPUTES

The parties have filed the following motions that are pending resolution:

1. Plaintiffs' Motion to Substitute Class Representatives (ECF 184);

2. Defendants' Motion *in Limine* to Exclude Trial Testimony of Certain Persons (ECF 186);
3. Defendants' Motion *in Limine* to Exclude Certain Opinions of Plaintiffs' Expert Witness (ECF 188);
4. Plaintiffs' Motion *in Limine* to Exclude Certain Policy Documents (ECF 190).

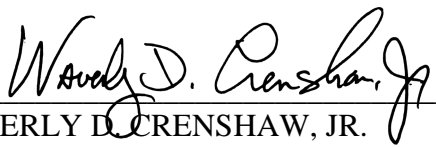
VIII. PROCEDURAL ISSUES

1. Plaintiff request that, due to his clinical practice schedule, Dr. Yao's testimony will be taken out of order on Friday, July 19, 2019.
2. The parties give notice to the Court that each party will be represented by more than two attorneys at trial.

IX. ESTIMATED LENGTH OF TRIAL

The parties estimate that the nonjury trial in this matter will last four days.

IT IS SO ORDERED.



WAVERLY D. CRENSHAW, JR.
CHIEF UNITED STATES DISTRICT JUDGE